

REMARKS

Applicants respectfully requests reconsideration of the instant application on the basis of newly amended claims and the accompanying Declaration of Dr. Lior Rosenberg and the below arguments.

35 U.S.C. § 112 Grounds for Rejection

The Examiner has rejected claims 14, 17, 22 and 29-32 as failing to comply with the written description requirement. Claims 14, 17, 22, and 31 have been amended to overcome the rejections. Claims 29, 30, and 32 have been cancelled.

35 U.S.C. § 103 Grounds for Rejection

The Examiner rejects claims 1-5, 9, 14-18, 21, 23, 24, and 27-32 under 35 USC §103(a) as being unpatentable over *Malodobry* (US2004/0111107) in view of *Bogart et al.* (US 5,271,943). Applicants respectfully traverse these rejections for the reasons discussed below.

A. The present invention as defined in the amended claim 1 is a method of removing pigmentation, specifically tattoos, from an area of skin. The method is based on two known facts: Firstly for mature tattoos the pigment particles that were injected into the dermis at the time the tattoo was created are mostly found inside of cells, which develop around the pigment particles within a few days of the creation of the tattoo. Secondly, the small diameter holes created by pricking the dermis with a needle close up naturally within a very short period of time.

Taking these facts into consideration, the method of the invention essentially comprises two steps:

Firstly the cells containing the pigments are mechanically destroyed by means of a needle in an analogous manner to that in which the tattoo was originally created “in order to liberate pigments and cellular fluids from within the cells”.

Secondly, after the skin has been punctured by the needles, a specially prepared pad is laid over the punctured area. The pad contains a material that has the property of “accelerating a process of migration of said pigments toward an outer layer of the skin”. The material is a hygroscopic material that draws the aqueous mixture containing the tattoo ink pigment fragments, cellular fluid, and cellular debris to the surface of the skin, where the mixture is absorbed into the pad.

The hygroscopic material, which is a salt-based granular paste, is located in the pad and not placed directly on the skin surface or introduced into the holes created by the needles in order to prevent injury to the skin and to insure that a sufficient pressure gradient will be maintained over time between the intercellular fluid in the dermis and the hygroscopic material in order to draw the pigment fragments to the surface.

B. The method taught by *Malodobry* appears to be superficially similar to that of the present invention since both are based on use of a machine similar/identical to a tattooing machine to penetrate the skin with one or more needles into the dermis where the tattoo pigments reside.

However, as acknowledged by the examiner, *Malodobry* does not teach the second step of the present invention. In this respect the office action states that: "*Malodobry* does disclose using irritants such as sodium chloride to increase exudates and thereby increase the amount of pigments migrating towards the outer layer (this is clearly the intent of using irritants as disclosed in paragraphs 0050-0052; Examiner notes that the use of irritants is disclosed immediately after *Malodobry* discloses an intent to use wound exudates to carry pigments to the skin surface; see paragraph 0049)."

In paragraphs 0050-0052 *Malodobry* teaches "application of so-called skin irritants to the skin surface or the direct introduction thereof into the agglomerates of the color pigment fragments before, during or after the mechanical destruction of the color pigment agglomerates".

- a) The examiner appears to conclude from this that *Malodobry* is teaching using these skin irritants to accelerate a process of migration of said pigments toward an outer layer of the skin as required by claim 1 of the present application.
- b) Applicant understands something entirely different from paragraphs 0050-0052. Applicant's understanding is that *Malodobry* uses the skin irritants to attempt to hinder the natural healing of the "wounds" caused by the needles, in this way to attempt keep the pin pricks open longer than would be the case in the absence of the skin irritants and thereby to allow more time for "The usual wound healing conveys the color pigment agglomerate fragments to the skin surface

where they are then scaled off” [0049].

c) This is not only the understanding of the applicant. In this regard the examiner is respectfully referred to section 17A of the Declaration in accordance with 37 CFR 1.132 that accompanies this response.

Malodobry teaches a passive approach, which relies on natural processes to cause the fragments to be carried to the skin surface. On the other hand the method of the present invention is an active approach, which requires use of a pad comprising a material which accelerates the migration of the pigments to the outer layer of the skin. As a result of actively drawing the pigments and cell fragments to the surface the number of particles that remain behind and are re-trapped in the dermis is greatly reduced.

C. *Bogart, et al.* is cited by the Examiner in order to show that: “It would have been obvious to one of ordinary skill in the art in view of *Bogart, et al.* to have used a pad and a paste as claimed for a number of reasons. The Examiner then lists three of these reasons:

- i. “*Malodobry* suggests using a sodium chloride irritant but does not give a specific method for applying it. The device and method of *Bogart et al.* would provide one of ordinary skill in the art with a specific device and method for implementing *Malodobry*’s suggestion of using a sodium chloride irritant to increase wound exudate or drainage.”
- ii. “One of ordinary skill in the art would also recognize that the device and method of *Bogart et al.* would especially enable the exudate to carry the pigments as intended by *Malodobry* because *Bogart et al.* teach

that their method would cause exudate to sweep bacteria to the outer layer and bacteria are as large or larger than the pigment agglomerates.”

iii. “One of ordinary skill in the art would at least be motivated to apply the method of *Bogart et al.* to heal the wound of *Malodobry* after the pigments are substantially removed. The step(s) provided by *Bogart et al.* could still be considered as part of the overall method of pigment removal.”

a) In the response to a previous office action the applicant argued that *Malodobry* presented a complete method for tattoo removal and that there was no reason to look further. Additionally, assuming that one of ordinary skill in the art had recognized a need to improve the methods described by *Malodobry* for applying skin irritants after pricking the skin with the needles, he would not have selected *Bogart et al.* as a source of information concerning such an improvement. These arguments will not be repeated herein, but in applicant's opinion they are still relevant and valid. In this regard the examiner is respectfully referred to sections 7 – 13 of the Declaration (Attachment B) in accordance with 37 CFR 1.132 that accompanies this response.

b) The first of the examiner's reasons relates to the question of motivation. With all due respect, applicant believes that the examiner is not correct in stating that *Malodobry* does not give a specific method for applying a sodium chloride irritant. *Malodobry* in paragraphs 0050, 0052, and claim 1 states that the skin irritant should be either introduced to the skin surface and/or introduced into the color pigment agglomerates. It seems obvious that the first method of applying

the skin irritant that is suggested by *Malodobry* is to simply spread it on the surface of the skin in the treated area and the second method involves using the needles to inject the irritant into the dermis. A way of performing the latter can be deduced from paragraph 0047, e.g. to replace the tattoo ink used in the process of creating the tattoo with a solution comprising the skin irritant. Therefore it is applicant's position that there would be no motivation for a person of average skill in the art to search for a different method of applying the skin irritants – the description in *Malodobry* relating to this aspect of his method is enabling. In this regard the examiner is respectfully referred to section 17E.i of the Declaration (Attachment B) in accordance with 37 CFR 1.132 that accompanies this response.

c) Regarding the examiner's second reason for combining *Malodobry* and *Bogart et al.* - Because of the difference of nature between the pin holes of *Malodobry* and the open wounds of *Bogart et al.* it is applicant's understanding that the gel of *Bogart et al.* could not act in the same way in the former as in the latter. In fact there is reason to believe that the gel of *Bogart et al.* would be incapable of entering the needle holes, much less descend into the region in which the pigment agglomerations are located. In this regard the examiner is respectfully referred to section 17E.ii of the Declaration (Attachment B) in accordance with 37 CFR 1.132 that accompanies this response.

d) Regarding the examiner's third reason for combining *Malodobry* and *Bogart et al.* – According to the examiner the reason for applying the gel of

Bogart et al. is to supply the method of *Malodobry* with the second step of the method of the present invention, i.e. "accelerating a process of migration of said pigments toward an outer layer of the skin". At the stage in which the tattoo has been nearly completed removed, i.e. "after the pigments are substantially removed" there is no need to accelerate their migration. Furthermore, there is no necessity for healing the wound of *Malodobry* since there is no wound – there are pin pricks which close naturally in a very short time. In this regard the examiner is respectfully referred to section 17E.iii of the Declaration (Attachment B) in accordance with 37 CFR 1.132 that accompanies this response.

D. As discussed above and in the attached Declaration, a person of ordinary skill in the art, upon becoming familiar with the teachings of *Malodobry* would find no motivation to search further for a way of improving it.

Nonetheless, if a person of ordinary skill in the art were asked to look for a way of improving the method of *Malodobry* and either discovered by himself or, more likely, was told that the way to improve *Malodobry's* method were to find a way of "accelerating a process of migration of said pigments toward an outer layer of the skin" he would not turn to *Bogart et al.* to teach him how to make this improvement.

Nonetheless, if despite this a person of ordinary skill in the art were asked to consider combining the teachings of *Bogart et al.* with those of *Malodobry*, he would conclude that, for the reasons discussed above and in the attached Declaration, the combination would not result in a method that comprises all of the features of the present invention as defined by independent claim 1. Therefore, claim 1 is inventive over the

combination of *Malodobry* and *Bogart et al.*, so are the dependent claims 2-5, 9, 14-18, 21, 23, 24, 27, 28, and 31 are patentable as well.

Claim Rejections - 35 USC § 103: The Examiner rejects claims 6, 7, 19, and 20 under 35 USC §103(a) as being unpatentable over *Malodobry* (US2004/0111107) in view of *Bogart et al.* (US 5,271,943) and further in view of *Garitano et al.* (US 2004/0158196).

As shown above, the combination of *Malodobry* and *Bogart et al.* do not teach the two limitations of the present invention as defined by independent claim 1. Since *Garitano et al.* does not relate to the feature of claim 1 that is not taught by the primary and secondary references and claims 6, 7, 19, and 20 are dependent upon claim 1, these claims are also inventive over the cited prior art.

Claim Rejections - 35 USC § 103: The Examiner rejects claim 22 under 35 USC §103(a) as being unpatentable over *Malodobry* (US2004/0111107) in view of *Bogart et al.* (US 5,271,943) and further in view of *Dosch et al.* (US 5,271,943).

As shown above, the combination of *Malodobry* and *Bogart et al.* does not teach the two limitations of the present invention as defined by independent claim 1. Since *Dosch et al.* does not relate to the feature of claim 1 that is not taught by the primary and secondary references and claim 22 is dependent upon claim 1, claim 22 is also inventive over the cited prior art.

Declaration: Attached as Attachment B are a Declaration in accordance with 37 CFR 1.132 signed by Professor Lior Rosenberg MD and a copy of his CV. The evidence of Dr. Rosenberg is submitted on behalf of Applicants to traverse the current rejections. Dr. Rosenberg's

declaration shows objective evidence of nonobviousness that is commensurate in scope with the claims. Dr. Rosenberg's Declaration further shows that if persons of ordinary skill in the art were aware of the teachings of the *Malodobry* and *Bogart et al.* references cited in the subject Office Action, then they would still be unable to solve the problem. Thus for the above reasons and based on the evidence of nonobviousness introduced into the record by Dr. Rosenberg, Applicants respectfully request the removal of the present rejections and the allowance of the claims as amended.

Further Arguments

It is improper to use hindsight having read the Applicant's disclosure to "pick and choose" among isolated prior art references to disparage the claimed invention. In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). Even where an invention is, as a whole, fully disclosed by a combination of prior art elements, such elements cannot be combined to defeat a patent as obvious unless the art teaches or suggests the desirability of making the combination. ASC Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 221 U.S.P.Q. 929 (Fed. Cir. 1984). Thus, the mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. In re Fritch, 972 F.2d 1260, U.S.P.Q.2d 1780 (Fed. Cir. 1992). Finally, it is the invention as a whole that is important. Focusing on the obviousness of substitutions and differences, instead of on the invention as a whole, is a legally improper way to simplify the often difficult determination of obviousness. Gillette Co. v. S. C Johnson & Son, Inc., 919 F. 2d 720, 16 U.S.P.Q. 1923 (Fed. Cir. 1990).

The various Dependent Claims that depend from independent Claim 1 or 28 are also not made obvious by *Malodobry* in view of *Bogart et al.* or others because they include the limitations of Claim 1 or 28 and add additional elements that further distinguish the art. Therefore, Applicant respectfully requests that Claims 1-31 be allowed.

The Examiner's rejection in essence is one of obviousness, and on this point it is believed that the decision in Lerner v. Child Guidance Products, Inc., 193 U.S.P.Q. 329, 330 (2d Cir. 1976) is on point. This case held that obviousness does not turn on subjective considerations. However, the question is not whether the subject matter of the claim was obvious to the Examiner, the Board of Appeals, or the court, but whether it would have been obvious to one of ordinary skill in the specific art. Here Applicants suggest that the Declaration of Dr. Rosenberg provides the evidence that the invention as claimed is nonobvious.

Further, reconsideration of this proposed combination is respectfully requested because there would be no reason to combine *Malodobry* with *Bogart et al.* or others in the manner suggested by the Examiner since each method or system is complete and functional in itself and since the systems themselves fail to suggest any such combination or that there would be any advantages in combining their teachings. As was stated in In re Sernaker, 217 U.S.P.Q. 1, 6 (CAFC 1983),

“[P]rior art references in combination do not make an invention obvious unless something in the prior art references would suggest the advantage to be derived from combining their teachings.”

As was further stated in Orthopedic Equipment Co., Inc. v. United States, 217 U.S.P.Q. 193, 199 (CAFC 1983),

“It is wrong to use the patent in suit [here the patent application] as a guide through the maze of prior art references, combining the right references in the right way to achieve the result of the claims in suit [here the claims in issue]. Monday morning

quarterbacking is quite improper when resolving the question of obviousness in a court of law [here the PTO].”

Accordingly the rejection of the claims on *Malodobry* and *Bogart et al.* or others is submitted to have been improper and reconsideration and withdrawal are respectfully requested.

In order to establish a prima facie case of obviousness, the prior art teachings must be sufficient to suggest making the substitution or modification necessary to make the claimed invention to one of ordinary skill in the art, In re Lahu, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1984), in the absence of applicant’s own disclosure. See also, In re Laskowski, 871 F.2d 115, 117, 10 USPQ2d 1397, 1398-99 (Fed. Cir. 1989) and Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985). The motivation to make a specific structure

“is not abstract, but practical, and is always related to the properties or uses one skilled in the art would expect the [structure] to have, if made.”

In re Gyurik, 596 F.2d 1012, 1018, 201 USPQ 552, 557 (CCPA 1979). See also Fromson v. Advance Offset Plate, Inc., 755 F.2d 1549, 1556, 225 USPQ 26, 31 (Fed. Cir. 1985)(“Critical inquiry is whether ‘there is something in the prior art as a whole to suggest the desirability, and, thus, the obviousness, of making the combination’”).

There must have been a reason apparent at the time the invention was made to a person of ordinary skill in the art for applying the teachings at hand to effect the modification necessary to reach the claimed invention in the manner proposed or the use of the teaching as evidence of obviousness will entail prohibited hindsight. Graham v. John Deere of Kansas City, 383 U.S. 1, 148 USPQ 459 (1966), and In re Nomiya, 509 F.2d 566, 184 USPQ 607 (CCPA 1975).

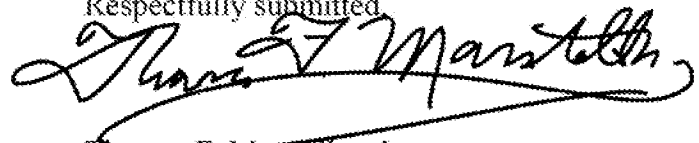
Here there is lacking the requisite suggestion in these prior art disclosures that would have motivated the artisan to do what the Examiner has characterized as being an obvious combination.

Conclusion

Applicant has now made an earnest attempt to place this case in condition for allowance. In light of the amendments and remarks set forth above, Applicant respectfully requests reconsideration and allowance of Claims 1-31.

If there are matters which can be discussed by telephone to further the prosecution of this Application, Applicant invites the Examiner to call the attorney at the number listed below at the Examiner's convenience.

Respectfully submitted,

A handwritten signature in black ink, reading "Thomas F. Marsteller, Jr.", with a large, sweeping underline that extends across the width of the signature.

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